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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,387	12/08/2003	Francis J. Giles	PHARMA-139	8138
23599	7590	05/24/2006	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DELACROIX MUIRHE, CYBILLE	
		ART UNIT	PAPER NUMBER	
		1614		

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/729,387	GILES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11,14,15,17-22 and 25-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6-10,14,15,17-21 and 25-48 is/are rejected.
- 7) Claim(s) 5,11,22 and 49-62 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

***Detailed Action***

The following is responsive to applicant's amendment and declarations received Oct. 19, 2005.

Claims 12-13, 16, 23, 24 are cancelled. New claims 26-62 are added. Claims 1-11, 14-15, 17-22, 25-62 are currently pending.

The previous claim objections set forth in paragraph 1 of the office action mailed April 19, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous rejection of claim 24 under 35 USC 112, first paragraph, set forth in paragraph 2 of the office action mailed April 19, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous rejection of claims 16 and 23 under 35 USC 112, second paragraph, set forth in paragraph 3 of the office action mailed April 19, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(a) over Nada et al., set forth in paragraph 4 of the office action mailed April 19, 2005 is withdrawn in view of applicant's declarations received Oct. 19, 2005. Applicant's declarations submitted pursuant to In re Katz received Oct. 19, 2005 is sufficient to overcome the claims rejection under 35 USC 102(a) over Nada et al.

The previous claim rejection under 35 USC 103(a) over Jolivet et al., 6,645,972 (paragraph 5 of the office action mailed April 19, 2005); the previous claim rejection under 35 USC 103(a) over Gourdeau et al., WO 00/57861 in view of the FDA article (paragraph 6 of the office action mailed April 19, 2005); and the previous rejection of claim 24 under 35 USC 103(a) over Chu et al., 5,817,667 in view of Zimmerman et al., WO 99/03854, paragraph 7 of the office

action mailed April 19, 2005) are withdrawn in view of applicant's amendment and the remarks contained therein.

Finally, the previous obviousness-type double patenting rejection set forth in paragraph 8 of the office action mailed April 19, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's amendment has necessitated the following new ground(s) of rejection.

***New Ground(s) of Rejection***

***Claim Rejection(s)—35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4, 6, 7, 8-10, 14, 15, 17-21, 25-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1, 14 and 15 adding –wherein said compound of Formula (I) and said Bcr-Abl kinase inhibitor are present in a synergistic ratio—introduces new matter into the claims. There is no support for synergism over the broad scope of compounds described in claims 1, 14 and 15. The specification provides support for synergism involving the combination of *two compounds*, beta-L-OddC and imatinib mesylate (STI-571) only. Please see page 9, lines 29-31; page 13, lines 28-31 and lines 36-37; page 26,

lines 34-37 and Table 1. Therefore, the amendment introduces new matter by rendering the claims broader than originally disclosed. One of ordinary skill in the art would not reasonably conclude that applicant had possession of the inventions as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 recites the limitation "A method according to claim 2" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 2 is pharmaceutical composition claim.

***Claim Objection(s)***

3. Claims 21, 22, 33-38, 52 are objected to because of the following informalities: in claims 21 and 22, line 3, the " s " at the end of "mesylates" should be deleted. In claim 33, line 4, the second occurrence of "2-butenyl" should be deleted. In claim 34, lines 4-5 and line 9, the second occurrence of "2-butenyl" should be deleted. In claim 35, line 4, the second occurrence of "2-butenyl" should be deleted. In claim 36, lines 4-5 and line 9, the second occurrence of "2-butenyl" should be deleted. In claim 37, line 4, the second occurrence of "2-butenyl" should be deleted. In claim 38, lines 4-5 and line 9, the second occurrence of "2-butenyl" should be deleted. Finally, claim 52 is objected to because it depends upon cancelled claim 16 . Appropriate correction is required.

4. Claims 5, 11, 22, 49-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Refer to page 26, Table 1 and Figures 12-14 for evidence of synergism between beta-L-OddC (i.e. Troxatyl™) and imatinib mesylate (STI-571).

***Conclusion***

Claims 1-4, 6, 7, 8-10, 14, 15, 17-21, 25-48 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Ardin Marschel**, can be reached on **571-272-0718**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM *CM*  
May 15, 2006

*Ardin H. Marschel 5/15/06*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**